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Owen-Smith, A; Coast, Joanna; Donovan, J

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The usefulness of NICE guidance in practice: Different perspectives of managers, clinicians, and patients

Amanda Owen-Smith

University of Bristol

Joanna Coast

University of Birmingham

Jenny Donovan

University of Bristol

Objectives: The UK National Institute for Health and Clinical Excellence (NICE) has been widely hailed as an international leader in health technology assessment. The objectives of its guidance are to ensure uniformity in healthcare provision, and promote a systematic and accountable way to allocate resources. However, research relating to the implementation of guidance is limited, and little is known about how it influences decision making at the consultation level or how useful it is to individual patients.

Methods: In-depth interviews were undertaken with professionals involved in healthcare provision at the community level, and with clinical professionals and patients providing or receiving care for morbid obesity and breast cancer ($n = 52$).

Results: Although NICE guidance was generally well-regarded, in practice it was of more importance and usefulness to managerial than clinical professionals. Clinicians used a patchy approach to implementation depending on whether recommendations accorded with their personal interpretation of the evidence available, and whether funding was available locally. Many patients had not heard of NICE, and clinical professionals did not alert them to its existence. Even where patients knew about relevant guidance, they were rarely able to use it to assert their right to treatment.

Conclusions: These findings challenge the perception that NICE guidance results in consistent and accountable decision making, and the limited accessibility and usefulness of guidance to patients suggests more information and support is needed at the point of provision if these objectives are to be achieved.

Keywords: NICE, Rationing, Guideline implementation, Doctor–patient relationships, Patient knowledge

The past 2 decades have seen an international proliferation in the establishment of bodies to assess the effectiveness of healthcare technologies, and the UK National Institute of Health and Clinical Excellence (NICE) celebrated its tenth birthday last year (13). NICE is a national, autonomous body, and, although funded as part of the National Health Service (NHS), operates independently from governmental control. NICE has the role of explicitly assessing the effectiveness and cost-effectiveness of new and (increasingly) existing healthcare technologies, along with drawing up expert guidelines for the treatment of particular health conditions, and issuing recommendations for the use of selected clinical and public health interventions (14). NICE issues recommendations to NHS bodies working at the meso level of healthcare provision throughout England and Wales, with particular importance being attached to the implementation of Technology Appraisal Guidance (TAGs), which is mandatory within three months of issue.

The establishment of NICE had two main objectives—to establish a more systematic and accountable way to set healthcare priorities, and to reduce area variation in the availability of healthcare (15). It has been hailed as a success at both a national and international level, and has repeatedly been acclaimed as a beacon model for health technology assessment (HTA) agencies around the world (9;21). NICE is particularly praised for its centralized approach to producing and disseminating guidance, its clear integration of cost-effectiveness into technology appraisals, and, latterly, its attempts to explicitly integrate social value judgments into the decision-making process through the establishment of a “Citizen’s Council” (9;15;21). Nevertheless, NICE has been a controversial body since its inception, and particular pieces of guidance come under frequent scrutiny in the popular and clinical media (13). In the academic literature, the NICE decision-making process has met several criticisms, including its heavy reliance on cost-utility analysis (4), its failure to take account of the opportunity costs of implementing guidance (1), and the lack of evidence-base for the cost-effectiveness threshold commonly used (11).

Research about the use of NICE guidance in practice remains limited. Evidence that does exist is mainly based on large-scale audits of drug and intervention usage, and suggests a steady overall increase in adherence although significant regional disparities in implementation remain (18–20). However, two of these studies are based solely on a consideration of guidance relating to cancer drugs, and detailed studies of the implementation of particular NICE recommendations suggest significant regional disparities in implementation persist (10;12).

Numerous studies in the United Kingdom and elsewhere have shown that the implementation of HTA guidance is heavily dependent on both its cost and the local availability of funding (6;7;20). Additionally, clinicians report that implementation is problematic where it conflicts with individual patient advocacy (2;6), and it is unknown to what extent it

is actually used in decision making at the consultation level. Little is known about the importance and usefulness of HTA guidance to individual patients, and Coulter (3) has argued that patients are likely to be poorly informed and resourced when it comes to using NICE guidance in practice.

This study reports findings from a qualitative study where the views of health service managers, public health professionals, clinicians, and patients were sought with regard to both how they regarded the role of NICE in theory, and how useful such guidance was to them in practice.

METHODOLOGY

This study was part of a broader research project investigating patients’ and healthcare providers’ experiences of, and preferences for, implicit and explicit healthcare rationing. The research design was structured around an initial interview study with professionals working at the community level of provision, and was followed by two case studies relating to the experiences of patients and clinical professionals of using or providing treatments for morbid obesity and breast cancer. Approval was obtained from relevant NHS ethics committees before fieldwork being undertaken.

For the community study, contributors were recruited using a snowballing approach based on the recommendation of key informants identified during the set up of the research. Views were sought regarding treatment areas that were currently the subject of contentious priority setting issues, and the selection of the two clinical case studies was based on these data. Several different professionals involved in the delivery of morbid obesity and breast cancer care were interviewed, including clinicians, specialist nurses, and allied healthcare professionals, and these professionals facilitated access to patients. Data were collected through in-depth interviews, which were audio-recorded and followed a brief topic guide (Table 1), which was developed on the basis of a literature review and amended as interviews progressed so that emergent themes could be followed up. Data analysis was carried out according to the methods of constant comparison (8), and data collection and analysis were carried out iteratively to ensure that emerging themes of interest could be followed up. Sampling was on-going until a full exploration of the themes relevant to the core research objective was achieved. A more detailed description of recruitment processes and data collection and analysis is reported elsewhere (16).

This study reports findings from those parts of interviews where informants were talking about their views regarding the role and status of NICE guidance and how it was used in practice, and findings related to other issues included in the interviews have been reported separately (16;17).

RESULTS

Two public health consultants, two primary care physicians, and seven healthcare managers were recruited to the

Table 1. Relevant Extracts from Interview Topic Guides

Managerial informants	Clinical professionals	Patients
To what extent do you think government health policies impact on your daily practice? <i>Encourage expansion and follow up on resource allocation points.</i>	What are the criteria for referral into this service/to have [treatment]? How far are resource issues influential in these decisions?	Were you offered any other treatments at various points? Would you have wanted to know if other treatments were available?
Is your work influenced by NICE recommendations? What do you think the role of NICE is – <i>follow up on consistency and transparency in resource allocation and ask for opinions.</i>	How do you decide who is a suitable candidate for [particular treatment]? <i>Probe use of external guidance and opinions relating to the role of NICE, etc.</i>	Was there ever an occasion when you were asking for more treatments than they were being given? What was your reaction to this? (Probe acceptance/protest/payment) <i>Probe any knowledge of NICE guidance / area variation in care.</i>
Is the move toward being more open about resource allocation decisions a good one? Why/why not?	If services are not funded on the NHS, should patients still be told that the service is available but not funded, or is it better for them to not know?	Do you think the clinicians involved have offered you all the treatments that are available? Would you have liked more information?
Who is most important in guiding your allocation decisions, e.g., central authorities, SHA, Trust managers?	Do patients 'know their rights' in terms of NICE guidance, etc.?	

NICE, National Institute for Health and Clinical Excellence.

Table 2. Summary of Informants

	Community level study	Case study 1 – Morbid obesity treatment	Case study 2 – Breast cancer treatment	Totals
Public health professionals	2	0	0	2
Funding managers	7	0	0	7
Clinical professionals	2	5	5	12
Patients	0	13	18	31
Total	11	18	23	52

community study. In addition, thirty-one patients and twelve clinical professionals involved in receiving or providing secondary care treatment for morbid obesity or breast cancer care were interviewed (see Table 2). The data revealed differences in how managerial professionals (under which we have categorized both public health professionals and funding managers), clinical professionals, and patients viewed NICE guidance, and their experience of using it in practice also varied.

Views and Experiences of Managerial Informants

Nearly all managerial informants were involved in ensuring local funding bodies fulfilled their legal obligations with regard to the implementation of NICE TAGs, and saw this guidance as of the utmost priority in the organization of local healthcare provision.

If it's a NICE drug . . . we'll always have the money - we just have to take it from somewhere else. (P7, funding manager)

Most managers had a positive view of NICE guidance, and five applauded its explicit and systematic approach to decision making.

In the past the NHS would have made rationing decisions based on arbitrary criteria, whereas now it's actually saying, "we've looked at the evidence and the cost per QALY." (P5, funding manager)

However, managerial informants also acknowledged several problems with NICE guidance. All but one criticized the lack of consideration of affordability, which sometimes resulted in the displacement of local priorities or the persistence of area variation in access to care.

Often it feels like NICE is committing NHS funding but not helping with the problem of inadequate funding. (P2, public health professional)

Additionally, two were suspicious that NICE guidance was sometimes subject to influence by bodies with vested interests, such as the government or the pharmaceutical industry.

What the health service has to do is make resource allocation decisions, which means choosing between do we do A or do we do B? NICE doesn't do that—NICE says, "with all these drug companies breathing down our necks . . . manipulating the public and threatening to sue us, should we say yes or no to this drug for this indication?" And they almost always say yes. (P20, public health professional)

Experiences in Practice

Despite their concerns around affordability, NICE guidance was often useful to managers, and three commented that it relieved their burden of decision making when it came to making judgments between competing claims on resources,

with the implication that it could help them to control the behavior of clinical professionals.

You'd think evidence-based prescribing would make life easier, but it ends up like a convention of religious zealots quoting different passages of the Bible at each other ... the NICE guidelines make it good because it's something written in stone ... you've got a piece of paper that says ... "we pay for this and we don't pay for that." (P3, funding manager)

Views and Experiences of Clinical Professionals

Few of the professionals interviewed were critical of the idea of NICE in theory, and the two primary care physicians particularly applauded the notion of evidence-based decision making, and ensuring patients had sufficient information about their entitlement to healthcare.

I think its [guidance] healthy in that it encourages patients and doctors to have an understanding about what constitutes a good standard of care for particular conditions. (P4, primary care physician)

However, two clinicians believed that NICE guidance was not always a true reflection of the available evidence, and one believed this was linked to pressure from particular interest groups.

I don't trust in the [NICE] process, because I can see what I think is undue pressure from the pharmaceutical companies, and undue pressure from the politicians. (P17, primary care physician)

Where professionals did not trust the reliability of NICE guidance, or simply did not agree with conclusions drawn, it was less likely to be implemented.

I think where we [GPs] perceive that NICE guidance has come up with politically correct statements, I think we are pretty skeptical and probably ignore it. For instance ... prescribing of obesity medications ... I don't think that's the right solution to those problems. (P17, primary care physician)

Experiences in Practice

Both primary care physicians interviewed found NICE guidance useful to assist their decision making in practice.

I'm not in a position as an individual to have the time to go into depth on all the research on a particular drug – and I certainly haven't got the skills required to make a balanced judgment on overall risk-benefit [and] cost-effectiveness. (P17, primary care physician)

However, guidance was of limited usefulness to those working in secondary care. For those working in breast cancer, guidance was not issued quickly enough to assist decision making on the latest drugs available, and, for morbid obesity professionals, local funding bodies were simply unable to provide the service recommended by NICE, meaning that additional local prioritization criteria needed to be applied.

Research is moving much faster than our ability to subsequently have bureaucratic organizations like NICE then collate and oversee all the data. (P14, specialist breast cancer clinician)

I've got somebody who it [NICE criteria] fits perfectly ... her body mass index is fine, her age is fine, she's got two comorbidities. ... No funding ... they [PCT] just haven't got the money. (P13, specialist obesity nurse)

Several professionals noted that the existence of NICE guidance can make it more difficult for them to resist patients' demands for treatments they believe are inappropriate, and two (P16, P17) commented that it can sometimes result in overtreatment.

Sometimes you end up in the ridiculous situation of actually feeling obliged to use a treatment because it's NICE approved, even if you don't think it's the best thing to do. (P16, specialist breast cancer clinician)

However, in other circumstances the availability of guidance made it easier for informants to ration treatments.

For us it's [NICE guidance] a good defense ... this week I've had somebody ... she clearly isn't fat enough for weight loss surgery, [but] rather than being cruel ... I can say well "you don't follow the national guidelines." (P13, specialist obesity nurse)

Only one clinician (P16) talked about NICE in terms of a rationing body that constrained her autonomy. However, she commented that she had normally been able to find ways around rationing decisions she disagreed with, and later suggested that guidance was sometimes useful to help her insist to managers that particular treatments are funded.

At least if things get NICE approval then we know we don't have to fight to use the treatment. (P16, specialist breast cancer clinician)

The Views of Patients

Although all thirty-one patient informants were aware that the health service faced resource shortages, and more than two-thirds were aware that their own treatment had been subject to rationing, informants rarely commented on NICE without the prompting of the researcher, and six explicitly confirmed that they had never heard of the organization.

I: Have you ever heard on the media anything about NICE, the National Institute of Clinical Excellence?

Patient 17: Who?

Many of those who said they had heard of NICE either did not know what it was, or misunderstood its role and confused it with that of the drug licensing body.

I: Have you ever heard of the National Institute of Clinical Excellence?

Patient 24: NICE? Yes I have ... on TV and everything ... isn't it they test the drug and that's when people go on trials?

This widespread lack of knowledge about NICE contradicted the expectations of nearly all managerial informants, and one clinician.

I: Have patients generally heard of things like NICE?

P14 (specialist clinician): They have ... of course they're aware, the whole country's aware.

It was only clear in six interviews that patients understood the role and function of NICE, and three of these informants worked for the health service themselves. These informants expressed mixed feelings with regard to the acceptability of guidance, and informants had deep-rooted concerns about the potential sacrifice of individual benefits in favor of societal ones.

I feel in a bit of a state of conflict about NICE ... somebody needs to take responsibility [for rationing] ... but where they make a decision about, "well this drug only helps a very tiny percentage of people ... and therefore should we be funding it?" ... It almost pulls into question the value of individuals' lives, and who has a right to place a value on that? (Patient 27)

Experiences in Practice

It was clear that NICE guidance was of no practical use to those patients who did not know it existed, or had insufficient information about how to access it. They were unlikely to be alerted to this information by clinicians, who seemed concerned this would result in demands for treatments they could not then provide, and none of those with morbid obesity had been directly alerted to relevant NICE guidance.

If they went to the NICE guidelines they'd say "well hold on, NICE says that I should be able to have it [weight reduction surgery]" ... [but] we haven't got the funding." (P6, specialist obesity clinician)

However, three patients (Pa3, Pa5, Pa9) had researched NICE guidance themselves before their initial consultation with their GP, and one (Pa30) had been indirectly alerted to its existence after seeing a copy of a communication between her GP and the local PCT. However, none of these patients had been able to use NICE guidance to successfully argue they were entitled to treatment.

It [NICE guidance] made no difference. (Pa30)

DISCUSSION

These data show that the views of professionals and patients were not particularly discordant when it came to theoretical views about NICE. However, in practice, recommendations were of more importance and usefulness to professionals working in managerial rather than clinical roles, and guidance was generally of little consequence to patients. Managerial informants saw the implementation of TAGs as crucial and routinely displaced other priorities to fund them, even where they personally believed opportunity costs of implementation were unjustified. However, clinical professionals applied a patchy approach to the implementation of NICE guidance, depending on whether it fitted with their personal opinion and interpretation of the evidence available, as well

as whether funding was available locally to provide care. It was notable that both managerial and clinical professionals regarded NICE guidance as a means to exert power over the other group on occasion, and theoretical views of the usefulness of guidance and the way it was used in practice did not always accord. For patients, guidance was of limited usefulness because several did not know that relevant guidance existed, and, even those who had used guidance to establish their eligibility for care were rarely able to assert their right to treatment.

The findings suggest that NICE guidance does not always fulfill its main objectives. The study provides evidence to support previous findings that regional variations in care persist because local funding is not always available to provide the care recommended by NICE (10;12). Additionally, several managers in this study commented that even where funding is made available, the pressure on resources means other service developments have to be abandoned, which would presumably result in different regional disparities. The findings from this study also provide some empirical backing to Coulter's (3) view that patients need further information about NICE guidance at the point of treatment if the concept of explicit rationing is to be fully embraced. However, the benefits of such a fully explicit approach need to be weighed against the implications of the finding that theoretical views on the acceptability of rationing are superseded by anger and distress when individual treatment is withheld (16).

Using qualitative techniques meant the researcher was able to elicit informants' often-conflicting opinions around the acceptability of NICE guidance, and could probe to what extent it was useful to these individuals in practice. Additionally, it provided scope to sensitively explore whether patients were aware of NICE guidance, and what they understood about its role and importance. However, such in-depth techniques inevitably affected the scope of the research, and, although the use of two clinical case studies was useful to provide some consistency by which to compare individual accounts, the extent to which the views and experiences of informants are typical of professionals and patients more broadly is unknown. A useful area for future research would be to explore the relevance of these findings to other clinical settings, with particular emphasis on further investigation of patients' views on the role of NICE, and the reasons for the patchy implementation of recommendations by clinical professionals. Additionally, it would be interesting to follow up the finding that guidance was seen as more important to managers than clinicians, and investigate whether healthcare professionals view NICE guidance as a mechanism to promote clinical excellence or merely as a tool to facilitate cost containment.

However, perhaps the most important priority for further inquiry is to find out how NICE guidance can be made more accessible to patients at the point of accessing care, to avoid the risk of it becoming simply another tool in the power

struggle between clinicians and managers when it comes to resource allocation. An understanding of how patients can understand and exert their rights to NHS care is also relevant to the effective implementation of the newly launched NHS constitution (5), where it seems likely that the same barriers to the accessibility and usefulness of information will exist.

CONCLUSION

This study showed that, at least in these two clinical areas, different stakeholders had widely diverging opinions on the status and importance of NICE guidance, and patients often either did not know about the existence of relevant guidance, or were unable to use it to access appropriate care. It is important to understand how guidance can be made more accessible and useful to patients at the point of need if explicit rationing is to be embraced, or at least to avoid social inequality in access to information about healthcare decision making, and potentially healthcare.

CONTACT INFORMATION

Amanda Owen-Smith, PhD (a.owen-smith@bris.ac.uk), Research Associate, Department of Social Medicine, University of Bristol, 39 Whatley Road, Bristol BS8 2PS, United Kingdom

Joanna Coast, PhD (j.coast@bham.ac.uk), Professor of Health Economics, Health Economics Unit, University of Birmingham, Public Health Building, Birmingham B15 2TT, United Kingdom

Jenny Donovan, PhD (jenny.donovan@bris.ac.uk), Head of Department, Department of Social Medicine, University of Bristol, 39 Whatley Road, Bristol BS8 2PS, United Kingdom

CONFLICT OF INTEREST

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